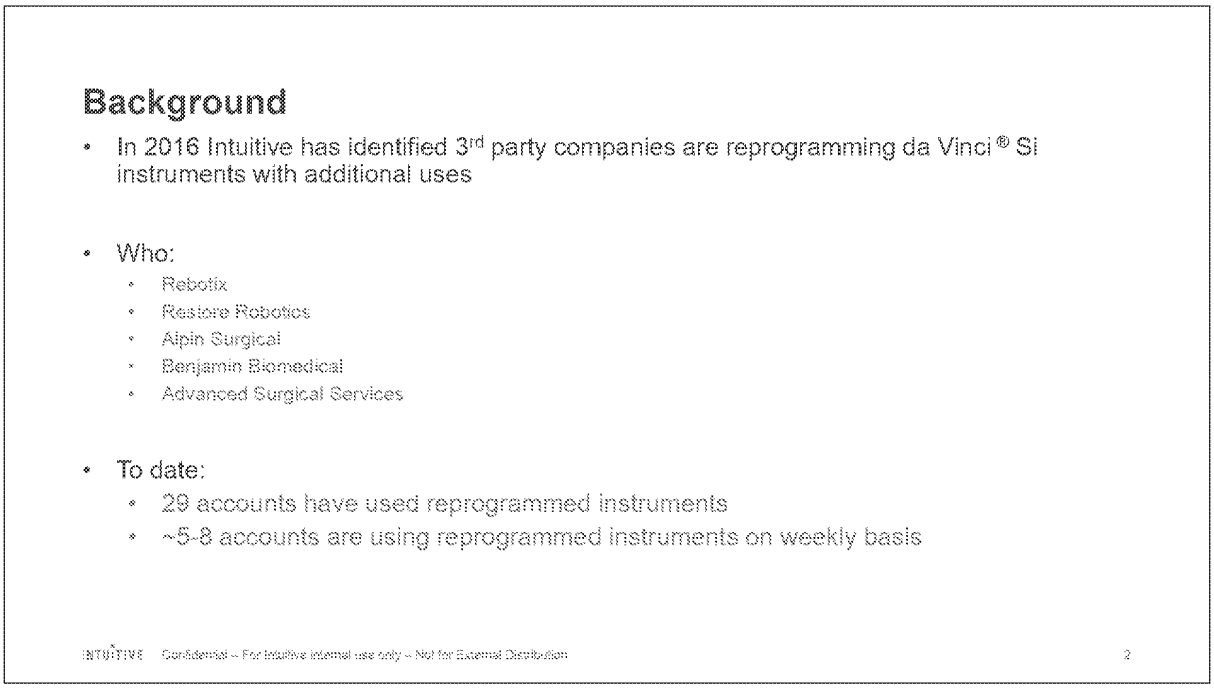
Unauthorized Instrument Reprogramming Overview



Background

- In 2016 Intuitive has identified 3rd party companies are reprogramming da Vinci® Si instruments with additional uses
- Who:
  - Rebotix
  - Restore Robotics
  - Alpin Surgical
  - Benjamin Biomedical
  - Advanced Surgical Services
- To date:
  - 29 accounts have used reprogrammed instruments
  - ~5-8 accounts are using reprogrammed instruments on weekly basis

Still trying to understand whether the companies are:
Selling the ability to local repair shops
Using the local repair shops as collection groups and performing the modification at a separate site

I added this slide for additional background

Background

US Patent issued for "Refurbishment of Robotic Surgical Arms"

- US 9,247,996 B1, issued Feb 2, 2016
- Describes "an exemplary robotic device…modified with an electrical circuit board having an *interceptor* system."

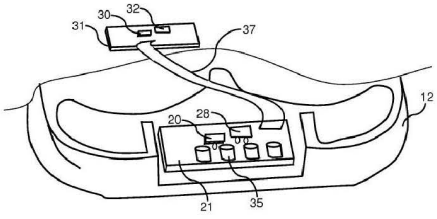


FIG. 7

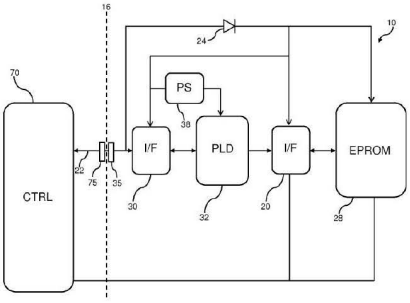
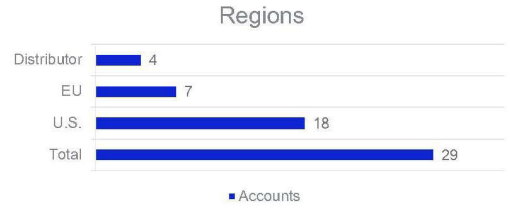


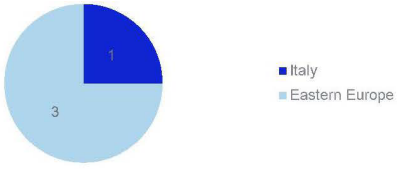
FIG. 4

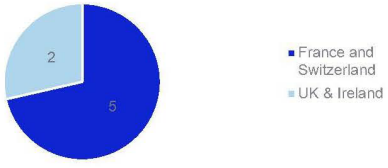
Still trying to understand whether the companies are:
Selling the ability to local repair shops
Using the local repair shops as collection groups and performing the modification at a separate site

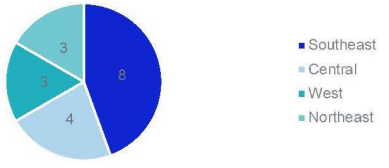
Accounts affected to date (since 2016)

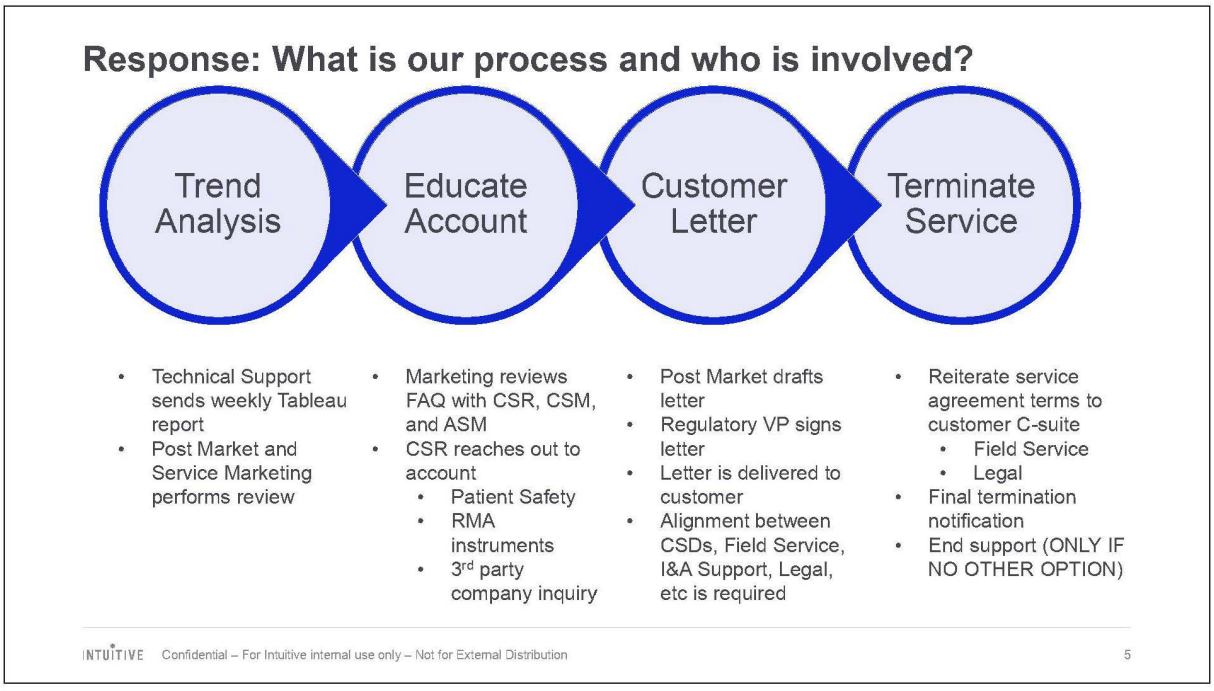
Perhaps add actual picture of adulterated instrument from RMA: Emily?











Constantly monitoring tableau reports to see if there's a trend at the customer site
If there is a trend, the Sales team is made aware of the corresponding da Vinci account and is asked to reach out to the account accordingly
If the account continues to use these unauthorized reprogrammed instruments, the sales team is asked to approach the account again. Usually once surgeons are aware of these instruments, they become our advocates to stop using the reprogrammed instruments.
The next escalation step would be our more formal action. A customer letter is created, signed by the VP of Regulatory and hand delivered to the account.
If all else fails we can discuss terminating their sales and service agreement because we can not under good conscience put patients at risk

Change in Direction

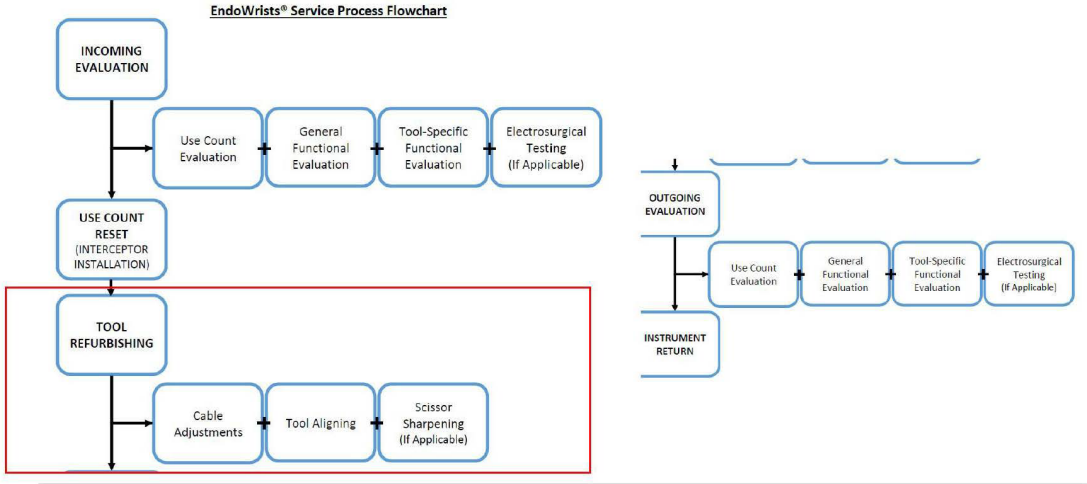
- 3rd Party Response:
  - [redacted]
  - FAQ rebuttals
- Next Steps for Intuitive
  - Comprehensive user documentation
  - [redacted]

Perhaps we separate Rebotix material into 2 categories:
1) Rebuttals against ISI
2) Claims of their validity

Rebotix presented Rebuttals against the OEM (ISI)

- Repair being performed is a "Service" [redacted]
- The instrument is "passive" and does not rely of data during surgery
- The number of lives were defined arbitrarily
- "Serviced" devices are inspected, repaired, and tested to ensure safety
- Quality system compliance

Rebotix Rebuttals



Rebotix Rebuttals

- *… As such, all Intuitive Surgical EndoWrist® products are rigorously tested, … to achieve a targeted level of safety, precision, and dexterity ... Beyond this .. useful life, the accumulated effects of normal wear and tear will impact the instrument's performance. This gradual degradation occurs both from use in surgery as well as repeated chemical and thermal exposure during the cleaning and sterilization cycles required between uses….*
- R1 - Regarding precision and dexterity - The precision and dexterity were validated in the surgical control system, not the instruments. The instruments are standard laparoscopic instruments adapted to be controlled by the host system instead of directly by the human hand.
- R2 - Regarding instrument degradation - …soft tissue forceps degrades as fast as an RF energized scissor …This would then lend itself …that the 10 uses is based on the weakest link….this weak-link theory is a direct contradiction to their validated "specific level of performance" statement. If one tool end receives far less wear, then it would be able to sustain a longer life in the acceptable "specific level of performance".

Rebotix Rebuttals

Unintuitive motion (i.e. instruments do not track well with master manipulators; sudden undesired motions or stalls

R3 - Sudden undesired motions could only be a flaw in the control system. …The instruments are passive accessories that only perform the directed actions of the surgeon. ..stalls or lack of range of motion could be a result of the instrument. However, this is a safe error state. This lack of motion would be predictable and observable … in no way, different from any manual laparoscopic instrument.

Insufficient grip force;

R4 - Grip force is controlled by the host system which relies only on the instruments cables being properly adjusted. This state is checked multiple times during the repair process and cables are tightened and aligned should they need it.

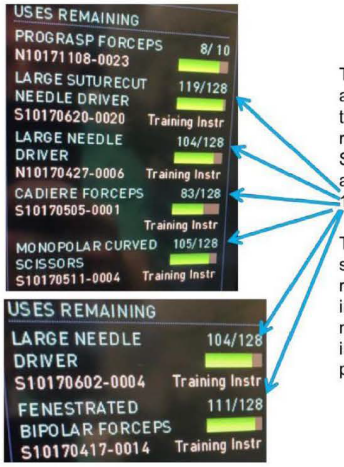
Dull or damaged scissor blades;

R5 - Damaged and dull scissor blades are an issue that affects all laparoscopic scissors, not just EndoWrists™. This issue has been being addressed in repairs for decades.

Broken/failed components; could result in fractured components

R6 - Fractures or breaks …have consistently been traced to misuse or mishandling, sometimes during sterilization. These faults …are not a function of instrument uses but of the design itself. No data has indicated that this kind of damage is any more likely for a serviced instrument.

Rebotix Rebuttals



These two images show a da Vinci surgical robot display of the Inventory Mode's listing of the remaining lives on instruments. Several of the training instruments are enabled to start with a total of 128 USES.

These instruments must be sterilized after every usage. Our research shows that the training instruments are built with the same materials and design as instruments used In surgical procedures.

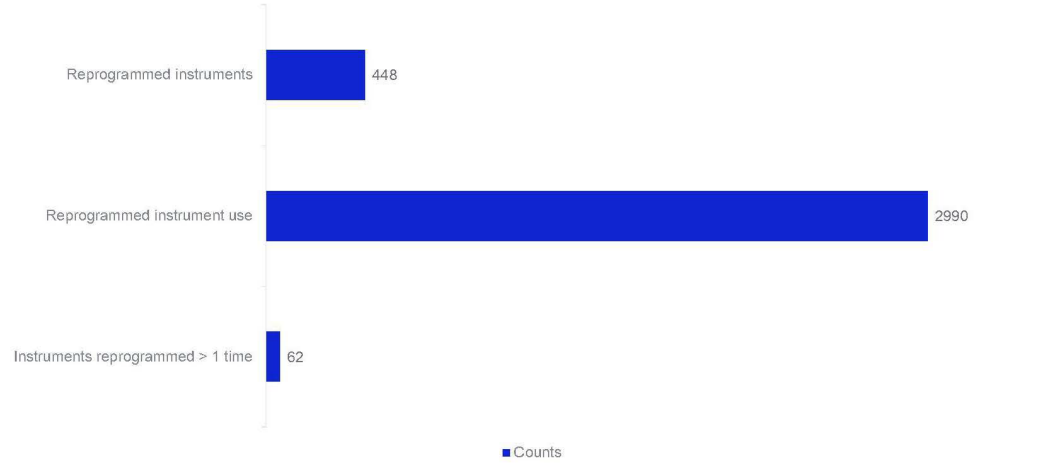
I added some bullet points below, and also added a section for Risk

Avenues

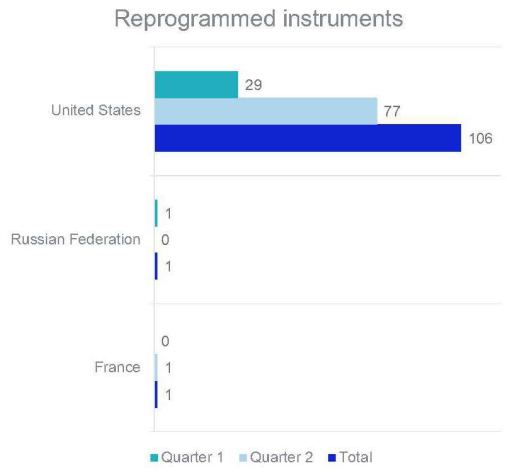
[redacted]

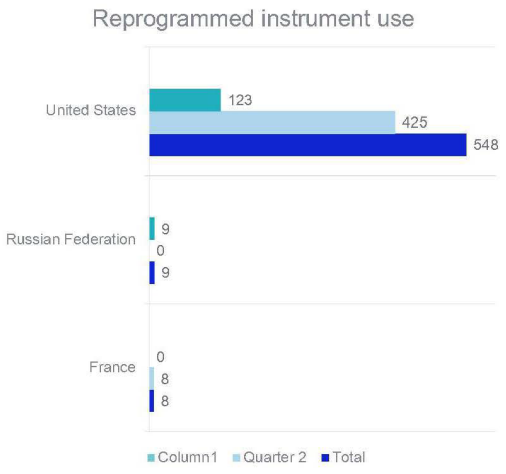
- Design & Mfg Testing
  - Instruments are NOT merely standard laparoscopic instruments; they are in fact highly specialized devices unique in our robotic application
  - Cable requirements (multi-jointed articulating wrist)
  - Material susceptibility
  - Electrical Safety
  - Device performance assessments include both system AND instrument
    - e.g. Guided Tool Change, Grip Cal
  - Performance degradation is expected over instrument useful life
    - e.g. cable stretch, composite epoxy maintube surface, cutting performance
  - Joint offsets cannot be simply be corrected in Xi instruments; offsets are measured and stored on the instrument; for SI instrument have more flexibility, but require specialized equipment (wrist nest, tensioner, IPT)
  - Re-sharpening issue
  - 100% Mfg Performance Testing
- Testing
  - Chemical integration
  - Soil accumulation
  - Stress cycles different per type of device (SSU/RC, etc)
  - Weibull Statistical Analysis – Risk based Confidence/Reliability requirements
  - Reprocessing Life
- Risk
  - High severity risks: Parts in patient, Stray energy, Unintuitive motion is not a safe error state
  - Ongoing monitoring?
  - FMEA: Severity and Occurrence & Detection
  - Assumed Liability
  - Interaction w/ other ISI instruments and accessories
  - Device History Record
  - Labeling

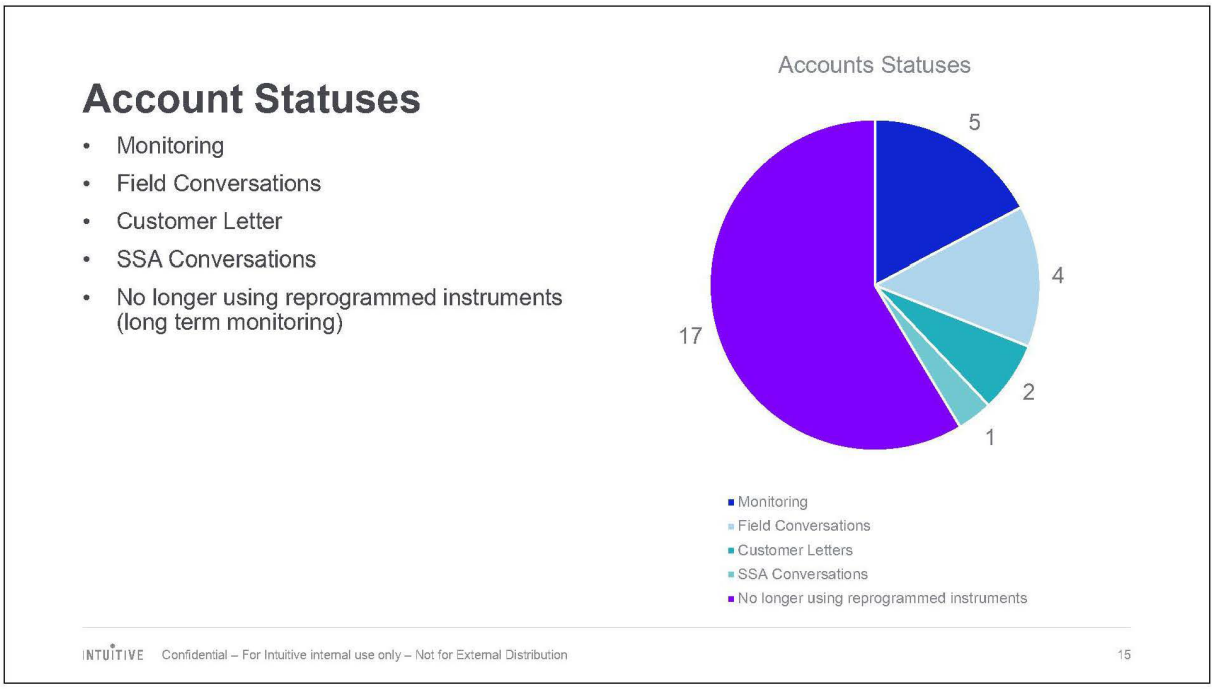
Reprogrammed instruments data to date (since 2016)



2019 data







Do we need to go into more detail than this?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